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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,742	10/22/2003	Kenneth Jacobs	00766.000091.10	8823

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/689,742	**Applicant(s)** JACOBS ET AL.	
	Examiner Rita Mitra	**Art Unit** 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 25 January 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☒ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

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The affidavit (Exhibit) will not be entered because applicant failed to provide a good reason why the affidavit is necessary.

Continuation of 11

A reconsideration request has been considered but does not place the application in condition for allowance because:

In response to **35 U.S.C. 101** rejection, applicants traverse the foregoing rejection and assert (page 4 of current 'Response') that at page 178, lines 27-32 of the specification, that clone bn97_1 shares activity with oxidized LDL (designated LOX-1). In particular, Applicants assert that the bn97_1 protein would share an activity of binding oxidized LDL, internalizing them into endothelial cells, and destroying them, and thus would play a crucial role in the pathogenesis of artherosclerosis.

However, in response it should be noted that, the specification fails to provide any sequence with such region, which is a structural characteristic of a bovine and human lectin-like receptor for oxidized low-density lipoprotein; or provides any activity of the polypeptide, which would be similar to the activity of a lectin-like receptor for oxidized low-density lipoprotein. Therefore, only on the basis of some sequence similarity to a lectin-like receptor protein, the protein of clone bn97_1 cannot be identified as a member of a lectin-like receptor protein family. Though the specification indicates that they may share at least some activity, this is a speculation.

Based on the specification (pages 87-89 and 177-178), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone bn97_1 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 210-226 of the specification. For example, the use of the polynucleotide for further research is described here (page 210). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed

polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

Applicants submit that the asserted utility is substantiated by the post-filing references, Swamuraet al., Nature, vol. 386, 1997, pp. 73-77 (Exhibit A). Applicants assert that it was determined on the basis of a sequence alignment between LOX1 and NKR-P1 that LOX1 belongs to the C-type lectin family (Fig. 4b). Further Applicants submit that clone bn97_1 is now known as CLEC-1 has identical coding sequences (Alignment submitted with the April 20, 2006 Amendment). The article in Eur. J. Immunol., vol. 30, pp. 697-704, 2000, describes CLEC-1 conserves the six cysteine residues that are typical of C-type lectins (see Fig. 2A), CLEC-1 **may** bind to lipoproteins, and **may** have a function of a scavenger receptor.

These references have been reviewed and Applicants' arguments are fully considered but not found persuasive.

Nature document and sequence alignment has been reviewed. The document indicates similarity between LOX1 and NKR-P1 protein, however on what basis Applicants submitting that bn97_1 belongs to C-type lectin family is not clear.

The Eur. J. Immunol. document indicates that CLEC-1 belongs to the C-type lectin superfamily, however on what basis Applicants submitting that bn97_1 is referred to CLEC-1 is not clear. Regarding sequence alignment, the specification fails to provide any sequence that which is a structural characteristic of a CLEC-1 protein that provides any activity of the polypeptide, which would be similar to the activity of the parent protein. Therefore, only on the basis of some sequence similarity the protein of clone bn97_1 cannot be identified as a member of CLEC-1 protein family.

Further while citing *In re Brana* Applicants assert that a post-filing reference can be used to refute any doubts about an asserted utility (see Kluge Declaration). The citation is not relevant because no where in *In re Brana* it is indicated that a post-filing reference can be used to refute any doubts about an asserted utility.

In regard to the rejection of the claims under **35 U.S.C., 112, 1st paragraph**, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation. Thus, Applicants arguments have not overcome the basis of this rejection for the reasons given above.

Rita Mitra, Ph. D.

March 19, 2007

Jon Weber
Supervisory Patent Examiner